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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,998	04/19/2001	Bertram Jacobs	A33781 - 072448.0308	8865

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.

09/837,998

Applicant(s)

JACOBS ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

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### Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/02 has been entered.

Applicants, in the response filed 10/11/02, indicate that the after final amendment filed 9/12/02 was not entered. **This is incorrect.** An examination of the advisory action mailed 10/7/02 clearly indicates that the **after final amendment was entered.**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Brandt et al.

This rejection is maintained for reasons of record in the previous Office Action (Paper 8, mailed 4/12/02) and for reasons outlined below.

Applicants again traverse this rejection by asserting that the correction of inventorship by addition of Teresa Brandt as an inventor is sufficient to remove the

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Brandt et al. reference as 102(a) art because the publication is now clearly applicants' own work. Applicants assert that a 102(a) rejection can be overcome by adding co-authors of a publication as inventors if the requirements of 35 USC 116 are met.

Applicant's arguments filed 10/11/02 have been fully considered but they are not persuasive. The examiner again notes that MPEP 2131.01 recites:

A prima facie case is made out under 35 U.S.C. 102(a) if, within 1 year of the filing date, the invention, or an obvious variant thereof, is described in a "printed publication" **whose authorship differs in any way from the inventive entity** (emphasis added) unless it is stated within the publication itself that the publication is describing the applicant's work. In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). See MPEP § 2128 for case law on what constitutes a "printed publication." Note that when the reference is a U.S. patent published within the year prior to the application filing date, a 35 U.S.C. 102(e) rejection should be made. See MPEP § 2136 - § 2136.05 for case law dealing with 102(e).

Additionally, it is noted that applicants are correct in stating that a 102(a) rejection can be overcome by adding co-authors of a publication as inventors if the requirements of 35 USC 116 are met. This would be effective if, by addition of the co-author(s), the inventorship is the same as the authorship of the publication. However, in the instant case, the addition of inventor Brandt does not result in the inventorship of the application being the same as the authorship of the publication. The rejection is therefore maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Beattie et al.

Applicants and Beattie et al. (Virus Genes, 1996, Vol. 12, pp. 89-94, see whole article, particularly the abstract, p. 90, right column, p. 92, right column and Fig. 2) recite expression vectors comprising a vaccinia virus deleted of the E3L gene wherein said vector further comprises exogenous DNA encoding an antigen (Beattie et al. recites the reovirus  $\sigma 3$  protein) operably linked to regulatory elements that control expression of said exogenous DNA and a carrier (i.e. a carrier involved in infecting cells with the vector). Both applicants and Beattie et al. also recite a method of making a recombinant gene product (Beattie et al. recites expression of  $\sigma 3$  reovirus protein) comprising subjecting the expression vector to conditions under which the recombinant gene is expressed. With regard to deletion of the E3L gene resulting in a reduced pathogenicity of the virus in animals, Beattie et al. notes (see p. 95, last paragraph) that viral genes encoding anti-apoptotic factors (such as E3L) result in longer cell survival times so as to ensure viral replication and transmission of progeny virus (and hence greater pathogenicity). Deletion of the E3L gene results in apoptosis of the infected cell and less transmission of viral progeny (reduced pathogenicity). Therefore, Beattie et al. teaches the claimed invention.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs (WO 99/55910).

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This rejection is maintained for reasons of record in Paper #6, mailed 10/23/01 and for reasons outlined below.

It is noted that this rejection was withdrawn as a result of applicants' arguments filed 2/12/02. However, as a result of further consideration, the rejection is re-instated. Applicants had argued that Jacobs et al. did not teach an expression vector comprising a vaccinia virus **with reduced pathogenicity in an animal host**. Applicants assert that since the E3L gene encodes dsRNA binding protein(s) that can inhibit apoptosis, a deletion of the E3L gene would induce apoptosis in host cells, thereby increasing pathogenicity.

This argument is not persuasive because applicants' argument that induction of apoptosis by the E3L deleted vaccinia virus would increase pathogenicity is not accurate in this case. On the contrary, the presence of a anti-apoptotic gene such as E3L would be expected to increase pathogenicity in a host animal because the anti-apoptotic functions of E3L delay the demise of the infected host cells long enough to ensure generation and transmission of progeny virus. Indeed, the apoptotic effect elicited by deletion of the E3L gene results in enhances interferon sensitivity which would be expected to result in killing of the infected cells prior to said cells being able to produce progeny virus and hence attenuate the virus *in vivo*.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Beattie et al.

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This rejection is maintained for reasons of record in Paper #6 and for reasons outlined below. This rejection was withdrawn as a result of applicants' arguments filed 2/12/02. However, as result of further consideration, the rejection is re-instated. Applicants had argued that Beattie et al. suggest that the Copenhagen strain VC-2 of vaccinia does not allow for animal testing and that since deletion of the E3L gene restricts host range, Beattie et al. teaches away from using the vaccinia virus with a deleted E2L gene as an expression vector.

These arguments are not persuasive because the examiner can find no teachings in the Beattie et al. reference which would teach away from using the Copenhagen strain in animals; indeed, applicants admit that the Copenhagen strain has served as a strain which can be engineered to be useful in the generation of human and veterinary vaccines (Specification, p. 5). Certainly, if a viral strain has been selected as the subject of extensive research on vaccine development, it is unclear how the skilled artisan would conclude that the same strain was too dangerous to be used in animals. In any case, this argument is irrelevant because the claims recite an expression vector with **reduced pathogenicity** in an animal host and clearly, deletion of the E3L gene would reduce pathogenicity in an animal host. With regard to Beattie et al. teaching away from use of the E3L minus vaccinia virus, it is noted that "The question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis" (MPEP 2131.05).

The Supplemental Oath filed 9/17/02 is acceptable.

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No Claims are allowed.

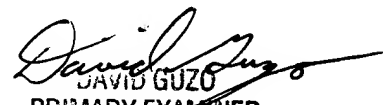
Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
April 11, 2003

  
DAVID GUZO  
PRIMARY EXAMINER